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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/370,860	08/09/99	KADURUGAMUWA	J 7933.36US01

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HM22/0703

EXAMINER

ZEMAN, R

ART UNIT	PAPER NUMBER
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1645

DATE MAILED:

07/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/370,860

Applicant(s)
Kadurugamuwa et al.

Examiner
Robert A. Zeman

Group Art Unit
1645



☒ Responsive to communication(s) filed on Apr 20, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) 7-17 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 and 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Priority

ω An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Election/Restriction

Applicant's election of Group I in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Additionally, the requirement for election of species as outlined in Paper No. 4 is withdrawn.

Claims 1-6 are pending and currently under examination. Claims 7-17 have been withdrawn from consideration.

Claim Objections

ω Claim 3 is objected to because of the following informalities: The period following the abbreviation for *Aeromonas* in *A. salmonicida* is missing. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 are rendered vague and indefinite by the use of the term “carrier strain”. It is unclear what is meant by said term. Is said carrier strain the source of the infectious agent? The membrane vesicles? Is said strain bacterial? Viral? As written it is impossible to determine the metes and bounds of the claimed invention.

Claim 3 is rendered vague and indefinite by the use of improper Markush language. It is suggested that of said claim be amended as follows: “microorganism is *Psuedomonas aeruginosa*,*A. salmonicida* **or** *Yersinia pestis*.” or alternatively “microorganism is selected from the group consisting of *Psuedomonas aeruginosa*,*A. salmonicida* **and** *Yersinia pestis*.”.

Claim 4 is rendered vague and indefinite by the recitation of the phrase “the membrane vesicle is a natural membrane vesicle of the microorganism containing outer membrane and periplasm components”. It is unclear what Applicant is claiming. Is it the membrane vesicles that must have both the outer membrane and periplasm components or just the microorganism or both? As written it is impossible to determine the metes and bounds of the claimed invention.

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Claim 5 is rendered vague and indefinite by the recitation of the phrase “a large membrane vesicle”. What size would differentiate a “large membrane vesicle” from a small membrane vesicle? As written it is impossible to determine the metes and bounds of the claimed invention.

Not addressed Claim 6 is rendered vague and indefinite by the recitation of the phrase “against another infectious agent” Is the vaccine itself an infectious agent? As written it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamstra et al. (WO 92/05194, IDS-6) in view of Viret et al. (EP 564 689, IDS-6) and Van Der Ley et al. (WO 94/08021, IDS-6).

Claims 1-6 are drawn to a vaccine against an infectious agent comprising a carrier strain having a membrane vesicle of a microorganism integrated into its cell surface, and wherein the membrane vesicle has an antigen associated with its surface.

Hamstra et al disclose vaccines against *Bordetella pertussis*, in which said vaccine comprises one or more outer membrane proteins in an outer membrane vesicle (OMV) formulation. Hamstra et al. further disclose methods for preparing said outer membrane vesicles comprising the resuspension of bacteria after growth, centrifugation and sonication on ice (see abstract and page 13). Hamstra et al. differs from the claimed invention in that they don't disclose a vaccine comprising a carrier strain having a membrane vesicle of a microorganism integrated into its cell surface, and wherein the said membrane vesicle has an antigen associated with its surface. Vietra et al. disclose strains of attenuated live recombinant bacteria that express O-serotype determinants of gram-negative enteric pathogens which are covalently bound to a lipopolysaccharide core. Viret et al further disclose that cloning and transfer of a compatible set of genes into a suitable vaccine strain, said vaccine strain will express a complete LPS structure with the O-antigen of the pathogen displayed on its membrane surface. Vietra et al. disclose that the immune system is stimulated by the displayed antigen eliciting a protective immune response (see page 4). Van Der Ley et al. disclose the use of outer membrane vesicles in combination with

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a group of polypeptides, with the immunoactivity of outer membrane proteins, bound to a membrane. Van Der Ley et al. further disclose vaccines comprising said membrane vesicles and lipopolysaccharides (see abstract).

Given that Hamstra et al. disclose vaccines against *Bordetella pertussis* which comprises one or more outer membrane proteins in a outer membrane vesicle (OMV) formulation; that Viret et al. disclose a method for expressing the O-antigen of a pathogen on the surface of a carrier strain; and that Van Der Ley et al. disclose vaccines comprising outer membrane vesicles and lipopolysaccharides, it would have been *prima facie* obvious to one of skill in the art at the time of the invention to have incorporated outer membrane vesicles into a vaccine formulation as disclosed by Hamstra et al. and Van Der Ley et al. and to further incorporate the membrane vesicle into the surface of a carrier strain as taught by Viret et al. One would have been motivated to produce such a vaccine due to of the success of Hamstra et al. and Van Der Ley et al in using membrane vesicles as vaccine components and the teaching of Viret et al. which sets forth that antigens expressed on the surface of a carrier strain stimulate the immune system and elicit a protective immune response.

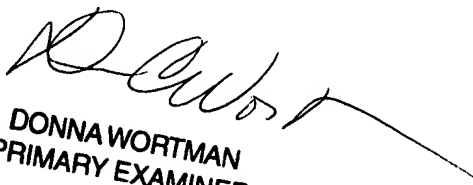
Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.


DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

June 29, 2000